K 031554

JUL 25 2003

Section X
510 (K) Summary of Substantial Equivalence

In accordance with the requirements of 21 CFR § 807, this summary is formatted with the Agency's final rule "....510(k) Summaries and 510(k) Statements...." and can be used to provide equivalence summary to anyone requesting it from the Agency.

Date Prepared: March 24, 2003

Manufacturer

Genzyme Biosurgery
A division of GENZYME CORPORATION
600 Airport Road
Fall River, MA 02720

Contact Person

Denise Lima
Phone: (508) 677-6439
Fax: (508) 677-6667
e-mail: denise.lima@genzyme.com

Device Information

Trade Name: Pleur-evac® Sahara Plus Continuous Reinfusion Autotransfusion System

Common Name: Continuous Reinfusion Autotransfusion System

Classification Name: Autotransfusion Apparatus
(per 21 CFR § 868.5830)

Indications for Use

The Pleur-evac Sahara Plus Continuous Reinfusion Autotransfusion System is indicated for use:

AUTOTRANSFUSION

1) for the collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in trauma and post operative situations

CHEST DRAINAGE

1) to evacuate air and/or fluid from the chest cavity or mediastrinum
2) to help prevent air and/or fluid from reaccumulating in the chest cavity or mediastinum
3) to help re-establish and maintain normal intrathoracic pressure gradients
4) to facilitate complete lung re-expansion to restore normal breathing dynamic.

Section X
510 (K) Summary of Substantial Equivalence

Device Description

The Pleur-evac Sahara Plus Continuous Reinfusion Autotransfusion System is a multi-chamber collection/reinfusion system. The Pleur-evac Sahara Plus Continuous Reinfusion Autotransfusion System is a sterile, single use devices intended for the collection of autologous blood (autotransfusion) and as chest drainage collection units.

Substantial Equivalence

The Pleur-evac Sahara Plus Continuous Reinfusion Autotransfusion System of this submission is similar in intended use, materials and performance characteristics of the currently marketed Pleur-evac Sahara Plus Continuous Reinfusion Autotransfusion System (#K963850).

The determination of substantial equivalence for this device was based on a detailed device description, performance testing and conformance with consensus and voluntary performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

Genzyme Biosurgery
c/o Ms. Denise Lima
600 Airport Road
Fall River, MA 02720

Re: K031554
Pleur-evac® Sahara Plus Continuous Reinfusion Autotransfusion System
Regulation Number: 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II (two)
Product Code: CAC
Dated: May 16, 2003
Received: May 19, 2003

Dear Ms. Lima:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known)

Device Name: Pleur-evac Sahara Plus Continuous Reinfusion Autotransfusion System

Section II
Indications for Use

Pleur-evac Sahara Plus Continuous Reinfusion Autotransfusion System is indicated for use:

AUTOTRANSFUSION

1) for the collection of autologous blood from the patient's pleural cavity or mediastinal area for reinfusion purposes in trauma and post operative situations.

CHEST DRAINAGE

2) to evacuate air and/or fluid from the chest cavity or mediastinum
3) to help prevent air and/or fluid from re-accumulating in the chest cavity or mediastinum
4) to help re-establish and maintain normal intrathoracic pressure gradients, and to facilitate complete lung re-expansion to restore normal breathing dynamics.

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031554

Prescription Use X OR Over-the-Counter Use ___
(Per 21 CFR § 801.109)

(Optional Format 1-2-96)